



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

NOV 23 1999

Ms. Nurul Aisyah Kong  
Quality Assurance Manager  
Hartalega Sdn. Bhd.  
9, Jalan Kuang Bulan  
Taman Kepong Industrial Estate  
52100 Kuala Lumpur, Malaysia

Re: K993722  
Trade Name: Blue Chlorinated Powder Free Latex  
Examination Gloves (With Protein Labeling Claim)  
Regulatory Class: I  
Product Code: LYY  
Dated: October 29, 1999  
Received: November 3, 1999

Dear Ms. Kong:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any

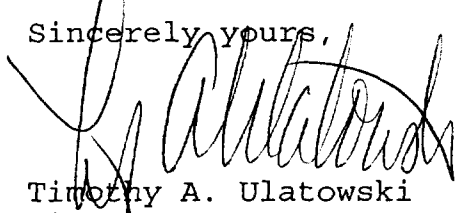
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obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4692. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsmamain.html>".

Sincerely yours,



Timothy A. Ulatowski  
Director  
Division of Dental, Infection Control  
and General Hospital Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

**INDICATIONS FOR USE**

**Applicant :** HARTALEGA SDN. BHD.

**510(k) Number (if known) :** 993722

**Device Name :** Blue Chlorinated Powder Free Latex Examination Gloves  
With Protein Content Labeling Claim of 50 micrograms or  
less.

**Indications For Use :**

**The patient examination gloves is a disposable device intended for  
medical and dental purposes that is worn on the hand of healthcare  
and similar personnel to prevent contamination between healthcare  
personnel and the patient.**

**( PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON  
ANOTHER PAGE IF NEEDED )**

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**Concurrence of CDRH, Office of Device Evaluation (ODE)**

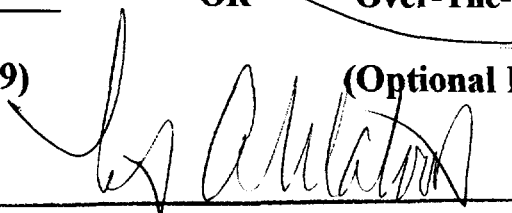
**Prescription Use** \_\_\_\_\_

**OR**

**Over-The-Counter Use**

**(Per 21 CFR 801.109)**

**(Optional Format 1-2-96)**

  
\_\_\_\_\_  
**(Division Sign-Off)**

**Division of Dental, Infection Control,  
and General Hospital Devices**

**510(k) Number** \_\_\_\_\_

K 993722